

IMI – 10th Call 2013

Evaluation of Stage 2

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Independent Observer's Report

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Abbreviations:

EoI - Expression of Interest

IO- Independent Observer

IE – Independent Experts

FPP – Full Project Proposal

EFPIA - European Federation of Pharmaceutical Industries and Associations

1. Background

This is the report of the independent observer (IO) for Stage 2 of the 10th Call for proposals by the Innovation Medicines Initiative (IMI).

The IMI 10th Call contained only one topic: “Immunological Assay Standardisation and Development for Use in Assessments of Correlates of Protection for Influenza Vaccines” and was launched on 29 October 2013.

Then a two-stage submission and evaluation process followed:

- Stage 1: Expressions of Interest (Eols)
- Stage 2: Full Project Proposals (FPPs)

For Call 10, there was only one eligible Eol that was submitted for evaluation. After Stage 1 evaluation, the applicant consortium was invited to form a Full Consortium with the corresponding EFPIA participants and to prepare and submit a Full Project Proposal (FPP) to IMI JU by 18 June 2014.

The submitted FPP was then remotely evaluated over a period from 20 June 2014 to 11 July 2014 by Independent Experts (IEs). The Independent Observer (IO) also had remote access to the submitted FPP. The IEs and Consortia, were then brought together in Brussels on July 15th, 2014 to finalise the Stage 2 evaluation process with a series of plenary, panel discussions and hearings.

The morning agenda was devoted to a general briefing and an introduction by the Moderator, then discussion of the FPP and preparation of the questions for the hearing. The afternoon was devoted to the hearing and discussion between the Panel and the Consortium followed by the finalisation of the Consensus Evaluation Report.

2. Overall Observations

The IO found that, as with the Stage 1, the Stage 2 evaluation was conducted professionally and fairly and according to the established procedures and regulations. The IO was struck by the dedication of all participants to ensuring an impartial and thoughtful evaluation of the FPP. The IMI team once again performed an outstanding job in publishing and publicizing the Call, organizing the FPP submission and evaluation process, contacting highly professional and well qualified experts and in putting together the onsite evaluation meeting.

The clarity of the onsite briefing for evaluators was especially appreciated as well as the excellent organization and coordination of the process. The IO was very pleased to see that the day process was set up according to the plan and the panel topic ran smoothly according to the pre-defined agenda.

In the IO opinion:

- The evaluation was carried out in full accordance with the applicable rules and published evaluation guidelines.
- Expert and ethical evaluators were of a high quality and possessed the relevant expertise to allow them to form an informed consensus on the merits of the proposed FPP.
- Evaluation of the proposal and the “face to face” discussions were fair and transparent.
- All IEs contributed to the hearing with the applicant Consortium.
- The hearing was very well conducted.
- The final Consensus Evaluation Report represents the consensus opinion of the panel.

3. Role and approach of the independent observer

3.1. Role of the independent observer

As stated in the IMI’s *Rules for submission, evaluation and selection of Expressions of Interest and Full Project Proposals, paragraph 3.4*, the role of the independent observers is as follows:

“The role of observers is to give independent advice to the IMI JU on the conduct and fairness of all phases of the evaluation sessions, on ways in which the experts apply the evaluation criteria, and on ways in which the procedures could be improved. As such, they shall verify that the procedures set out or referred to in these Rules are adhered to, and report their findings and recommendations to the IMI JU. They are also encouraged to enter into informal

discussions with the IMI JU staff involved in the evaluation sessions and to suggest to the IMI JU any possible improvements that could be put into practice immediately. However, in the framework of their work, they should not express views on the expressions of interest and full project proposals under evaluation or the experts' opinions on the proposals.”

3.2 Working methods of independent observers

In performing the task, the IO had access to all written information supporting the Stage 2 evaluation process. The IO attended the evaluation day. During the evaluation session, the IO attended the briefing session, sat-in during the panel discussions, and spoke individually with many of the expert evaluators. The IO also had ample chance to speak with IMI employees, including the Scientific Officers acting as moderators and the IMI lawyer present during the evaluation.

4. Observations and recommendations

The following sections record the IO observations on the stage 2 evaluation process and collate comments that were received from participants during the day of the meeting.

In general, the IO thinks that the evaluation process was well conducted and of excellent quality, implemented in fairness and conformed to international standards of peer-review.

4.1. The Call

The length of time between launch and deadline for the submission of FPP was in line with that of previous Calls. As stated above, the arrangements and execution of the evaluations were expertly undertaken.

4.2. Guidance to applicants

Like in previous calls and as already reported in previous IOs' reports, the applicant Consortium had, in the opinion of the evaluation panels, attempted to adhere closely to the demands of the Call.

4.3. Expert evaluation panels

IEs in the evaluation panel were selected and invited by the IMI JU as described in “Rules for submission, evaluation and selection of Expression of Interest and Full Proposals, 3.2”. All IEs fulfilled the required criteria.

All of the evaluation panel members had previously reviewed and attended the

Stage 1 evaluation.

Evaluators were, at the time of the “face-to-face” meeting, familiar with the FPP and the considerations and comments of the Panel following Stage 1. Panel members were aware of the nature and goals of the evaluation process, their responsibilities, the choices available to them and the consequences of their decisions and recommendations.

The scientific expert panel discussions consisted of:

- Each panel member being invited by the IMI Chairperson, to introduce themselves.
- The rapporteur responsible for the writing of the Consensus Evaluation Report and appointed prior to the meeting, being invited to briefly describe the key points of the FPP and any concerns and observations she had about the proposal.
- Other panel members were then invited in turn to give their views on the proposal and what issues might benefit from additional information from the for each topic in order of importance.
- Consortium members were invited to a hearing in order to give a presentation on their proposal and then answer the collated questions in front of the panel.
- The expert evaluators then finalized their recommendations and the Consensus Evaluation report, based on the earlier discussion and the answers provided by the consortium members.

The ethics expert panel discussion was similar to the one of the scientific review panel and ran in parallel with it. A small set of questions were selected by the ethics expert panel and transferred to the scientific panel by an IMI officer. Ethics experts could participate as observers during the hearing. However, even if both panels were present in the same venue at the same time, there was no formal opportunity for them to meet and discuss the proposals or raise potential issues of common concern or interest.

RECOMMENDATION: To increase the value of the non-scientific review, it is recommended that both expert panels met for a short period of time (30 minutes) before the hearing, and before questions are sent to the consortium members, in order to discuss potential issues of common concern or interest. The ethical and scientific aspects of the proposals should not be viewed as separate entities either by the panels or the consortium members.

In general, all IEs brought considerable knowledge and understanding of the issues to the Panel evaluations. All reviewers took an active role in the preliminary discussions and the drafting of the collated questions prior to the hearing. The IMI moderator and wider on site Secretariat, gave considerable support to all involved parties.

4.4. Timelines

The time allotted for remote evaluation of the FPPs appeared adequate.

4.5. Moderation of the expert evaluation panels

The expert evaluation panel was moderated by the appointed IMI's Scientific Officer. The moderating Scientific Officer was given considerable support by other members of the IMI Executive office. A dedicated IT officer and a member of the legal team were available throughout the session.

This difficult role was done with tact, professionalism and impartiality. Where needed, advice was given on process and compliance with regulations. No issues arose concerning the moderation or direction of the evaluation team.

4.6. Choice of Rapporteur

The rapporteur for the FPP was an IE chosen to present it to the evaluation panel and then contribute to the writing of the Consensus Evaluation Report for that FPP. This is an important role, with a direct impact on the discussions in the Panels. The assignment of a rapporteur also helps to streamline the process and brings focus to the IE group. The rapporteur was pre-assigned prior to arriving in Brussels, giving her time to prepare for this role.

4.7. Remote evaluation

The panel had approximately three weeks to evaluate the FPP remotely. This process worked well with the IEs providing full reports prior to the Brussels meeting. One IE was not able to be present at the evaluation sessions in Brussels, but his comments were readily available to everyone and the Scientific Officer made sure they were taken into account through the discussions. In general, no problems were reported in the viewing of the FPP, the supporting IMI Guidance or the subsequent uploading of the IEs' reports.

4.8. The evaluation tool

The online submission and evaluation system, SOFIA functioned well during the remote evaluation and the writing / uploading of the Consensus Reports. Some of the IEs flagged that the size of the font used in SOFIA is somewhat small and could be increased to ease reading.

RECOMMENDATION: Ensure the size of the font used in SOFIA or in documents printed from SOFIA for the day of the meeting is large enough for easy and convenient reading by the IE.

4.9. Overall Conclusions and Comments

There were no apparent violations of the applicable rules and published Guidelines and the evaluations, and discussions were fair and transparent. The IO attests that all procedures have been fully respected.

5. **Acknowledgements**

The IO was helped in her task by all participants in the Stage 2 consensus meeting. The IO thanks all IEs for being amenable to being 'observed' and for the formal and informal conversations that helped formulate this report. The IO further gratefully thank the IMI staff for their help, competence, hospitality and excellent professionalism both during and after the stay of the IO in Brussels in scientific, organizational, procedural and logistics matters.

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